

Claims

*Sub R2*

1. Oxaliplatinum stable pharmaceutical preparation for parenteral administration, characterized in that the oxaliplatinum is contained in a solution in a solvent at a concentration of at least 7 mg/ml and in that said solvent comprises a sufficient quantity of a hydroxylated derivative selected among 1,2-propanediol, glycerol, maltitol, saccharose and inositol.

2. Pharmaceutical preparation according to claim 1, characterized in that the oxaliplatinum is contained in a solution in said solvent at a concentration of at least 9 mg/ml and in that 1 ml of said solvent comprises at least 100 mg of one or several of said hydroxylated derivatives.

3. Pharmaceutical preparation according to claim 2, characterized in that said solvent comprises besides water.

4. Pharmaceutical preparation according to claim 3, characterized in that the oxaliplatinum is contained in a solution in said solvent at a concentration comprised between about 10 mg/ml and about 15 mg/ml.

*Sub R2*

5. Pharmaceutical preparation according to any of the previous claims, characterized in that it is packed in an appropriate container for parenteral administration.

6. Pharmaceutical preparation according to claim 5, characterized in that said container is a multidoses flask.

7. Pharmaceutical preparation according to claim 5, characterized in that said container is a prefilled syringe.

8. Pharmaceutical preparation according to claim 5, characterized in that said container is a soft perfusion bag.

*Sab R*

9. Pharmaceutical preparation according to claim 5, characterized in that said container is an ampoule.

*Sab AB*

10. Method for the preparation of a pharmaceutical preparation according to any of the previous claims comprising a step of mixing oxaliplatinum with a solvent comprising a sufficient quantity of at least one hydroxylated derivative selected among 1,2-propanediol, glycerol, maltitol, saccharose and inositol.

*Sab AB*

11. Method according to claim 10, characterized in that it comprises the following steps:

- a) put in contact at a temperature inferior to 80°C a quantity of oxaliplatinum with a sufficient quantity of the said solvent to obtain an oxaliplatinum concentration of at least 7 mg/ml;
- b) establish the mixture obtained at the step a) at a temperature comprised between 15-30°C;
- c) submit the mixture obtained at the step b) to an aseptic filtration; and
- d) the conservation in an adapted container for a parenteral administration of the mixture obtained at the step c) at a temperature comprised between 2-30°C.

*Sab AB*

12. Use of a multidoses flask to preserve the pharmaceutical preparation according to any of the claims 1 to 4.

*Sab AB*

13. Use of a prefilled syringe to preserve and/or manipulate the pharmaceutical preparation according to any of the claims 1 to 4.

*Sab AB*

14. Use of a soft perfusion bag to preserve and/or manipulate the pharmaceutical preparation according to any of the claims 1 to 4.